

Errata – FDA Briefing Package

The FDA briefing package (completed on April 1, 2001) represents preliminary analyses by the Division of Anti-Infective Drug Products of data received from the applicant as of March 25, 2001. For final results of these analyses, please refer to final medical and statistical reviews available under the Freedom of Information Act.

The following errata for the FDA briefing package should be noted:

p. 10, last paragraph - should read “Nine clinical trial sites were investigated by the FDA’s Division of Scientific Investigation. Six of these sites (representing 4 investigators) failed to meet good clinical practice guidelines and were therefore censored by the Agency due to data integrity issues . . .”

p. 12, Table 6 - For studies 3001 and 3006, ‘7-10 d’ should read ‘10 d’.

p. 13, Table 7A - For study 3001, the upper bound of the 95% CI for the PPc analysis should be 11.1 rather than 1.1. For study 3006, for the PPc analysis, the response rates should be 88.3% for telithromycin and 88.5% for clarithromycin. The 95% CI is (-7.9, 7.5).

p. 19, CAP efficacy summary, 1st bullet - ‘amoxicillin/clavulanic acid’ should read ‘amoxicillin’.

p. 20, Table 11 - Under 3003 Treatment Regimen, ‘Amoxicillin 250 mg’ should read ‘Amoxicillin 500 mg’.

p. 25, Table 25 – Incidence rates for abdominal pain and dyspepsia are reversed.

p. 37, 2nd paragraph - “3.29 mg/L” should read “3.72 mg/L.”

p. 38, 1st paragraph – The statement that ‘The applicant did not conduct analyses of QTf’ should read “The applicant did not conduct regression analyses of QTf and telithromycin concentrations.”

p. 39, Table 32, footnote B – ‘Telithromycin’ should read ‘ketoconazole’.

p. 43, 7th paragraph – Paragraph should read “A telithromycin-treated patient with a history of coronary artery disease and chronic obstructive pulmonary disease died on study day 4 of circulatory failure, respiratory failure, and kidney failure. Sputum cultures grew *S. pneumoniae*, β -lactamase-producing *H. influenzae*, and telithromycin-resistant *S. aureus*. This patient was considered a therapeutic failure because of the need to change her therapy from telithromycin to intravenous ceftriaxone and gentamicin.”

p. 47, 2nd paragraph – ‘CYP2D4’ should read ‘CYP2D6’.